



#10  
8-3-98

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Eugen Koren and Mirna Koscec

Serial No.: 08/765,324 Group Art Unit: 1817

Filed: December 24, 1996 Examiner: P. Duffy

For: ANTIBODIES TO LIPOPROTEINS AND APOLIPOPROTEINS  
AND METHODS OF USE THEREOF

Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

**DECLARATION OF AVAILABILITY OF DEPOSIT**

Sir:

I, Patrea L. Pabst, representing the assignee of the above-identified application, the Oklahoma Medical Research Foundation, hereby declare that:

1. The hybridomas described at pages 51-52 and claim 4 of the application, HB<sub>3</sub>cB<sub>3</sub>, and at page 74 and claim 5 of the application, RCB<sub>3</sub>M<sub>1</sub>D<sub>4</sub>, were deposited by the Oklahoma Medical Research Foundation, the assignee of the above-identified application, with the American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD, prior to filing of the priority application, U.S. Serial NO. 08/268,809, on April 8, 1994. The deposits were assigned ATCC numbers HB11612 and 69602, respectively.

SERIAL NO: 08/765,324  
FILING DATE: December 24, 1996  
DECLARATION OF AVAILABILITY OF DEPOSIT

2. The Oklahoma Medical Research Foundation and the inventors have contracted with the American Type Culture Collection, and agreed pursuant to 35 U.S.C. §112 and MPEP §608.01(p) (C), that:

- (a) during the pendency of the application in the U.S. Patent and Trademark Office, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request of the deposit or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become not viable.

3. The contract with the ATCC and deposit forms are attached.

SERIAL NO: 08/765,324  
FILING DATE: December 24, 1996  
DECLARATION OF AVAILABILITY OF DEPOSIT

4. I declare that all statements made herein of my own knowledge are true. These statements are made with the knowledge that willful false statements are punishable by fine or imprisonment under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



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Patrea L. Pabst  
Registration No. 31,284

Date: July 21, 1998

# American Type Culture Collection

1120 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301) 251-6328 Telec: 898-455 ATCCNORTH • FAX: 301-770-3573

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

**INTERNATIONAL FORM**

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Dr. Eugen Koren  
Oklahoma Medical Research Foundation  
825 NE 18th Street  
Oklahoma City, OK 73104

Deposited on Behalf of: Dr. Eugen Koren, Oklahoma Medical Research Foundation

Identification Reference by Depositor: ATCC Designation

*Escherichia coli* (FTG 1), R<sub>c</sub>B, M<sub>c</sub>D<sub>c</sub>,  
Murine hybridoma cell line, HB<sub>c</sub>CB<sub>c</sub>

69602  
HB 11612

The deposit was accompanied by:  a scientific description  a proposed taxonomic description indicated above.

The deposit was received April 8, 1994 by this International Depository Authority and has been accepted.

**AT YOUR REQUEST:**

We will not inform you of requests for the strain.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested April 12, 1994. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Bobbie A. Brandon Date: April 12, 1994  
Bobbie A. Brandon, Head, ATCC Patent Depository

Budapest Treaty DepositsAmerican Type Culture Collection

1734 Parklawn Drive • Rockville, MD 20851 USA • Telephone: (301) 435-4444 Telex: 321-542 ATCC DOVE • FAX: (301) 770-3387

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF  
 BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE  
 DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

\*1. Name of deposit (microorganism, cell, seed, plasmid, etc.) E. coli (TG 1)2. Strain designation given by the depositor (number, symbol, etc.) RcB3M1D43. Is this an original deposit under the Budapest Treaty? Yes4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty? (If so, indicate ATCC designation.) No5. Is this deposit a mixture of microorganisms or cells? No

6. Details and conditions necessary for the cultivation of the strain, for its storage and for testing for viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence. Recultivation overnight at 30°C in SOB medium containing 0.1 mg/ml ampicillin and 0.1 M glucose (SOBAG). Alternatively, reculture on 1.5% Bacto Agar-SOBAG plates at 30°C overnight.

7. An indication of the properties of the strain which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties. The depositor is not aware of any health or environment risk out of ordinary risks inherent to E.coli.

8. It is recommended that sufficient description be provided to allow the ATCC to confirm that the strain deposited generally conforms to that which the depositor states is being deposited (i.e., Gram negative rod).

Gram negative rod

a. For cell culture deposits please complete. Is the cell being cultured in the presence of antibiotic? (If so list the antibiotics)

b. For hybridoma deposits please complete. What is the isotype of antibody produced?

9. Is this strain zoopathogenic? phytopathogenic10. Does this strain contain plasmids relevant to the patent process? Yes  
 If so, what physical containment level is required [National Institutes of Health Guidelines involving Recombinant DNA Molecules (i.e., P1, P2, P3 and P4 facility)?] P1

11. Isolated from?

\*The answers to these questions are recommended but not required.

FOR ATCC USE ONLY	
ATCC DESIGNATION _____	
DATE CULTURE RECEIVED _____	
DATE VIABILITY TEST COMPLETED _____	

NOTE: 10 years' storage \$600 + 10 years' validation \$130 + Viability testing \$100 to \$150 depends upon location. • Expedited ATCC review \$15 • Return sample for approval if not culturable strain or living added \$30 • Prepare additional samples of cells/hybridomas \$50  
 \*TOURAGE cultures are stored for 10 years from date of deposit and for one year after the last request for a sample, as required under the rules of patent offices in most countries.  
 Form BP/1 (Rev. 1 of 2)

# American Type Culture Collection

1000 Parklawn Drive • Rockville, MD 20850 USA • Telephone (301) 435-1240 Telex 330-744 ATCCROVE • FAX: 301-774-2527

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF  
 BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE  
 DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

\*1. Name of deposit (microorganism, cell, seed, plasmid, etc.) Murine Hybridoma cell line

2. Strain designation given by the depositor (number, symbol, etc.) HB3CB3

3. Is this an original deposit under the Budapest Treaty? Yes

4. Is this a request for a conversion of a deposit already at the ATCC to meet the requirements of the Budapest Treaty? (If no, indicate ATCC designation.) No

5. Is this deposit a mixture of microorganisms or cells? No

6. Details and conditions necessary for the cultivation of the strain, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence.

Reculture in RPMI 1640 + 10% fetal bovine serum + L-glutamine (5mM) + Penicillin (100units/ml)  
+ streptomycin (100 mcg/ml)

7. An indication of the properties of the strain which may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties. The depositor is not aware of any health or environmental risks

8. It is recommended that sufficient description be provided to allow the ATCC to confirm that the strain deposited generally conforms to that which the depositor states is being deposited (i.e. Gram negative rod).

Round shaped hybridoma cells slightly adherent

a. For cell culture deposits please complete. If the cell being cultured in the presence of antibiotics (if so list the antibiotics) Penicillin 100 units/ml, Streptomycin 100 mcg/ml

b. For hybridoma deposits please complete. What is the isotype of antibody produced? IgG1 (kappa)

9. Is this strain zoopathogenic? phytopathogenic?

10. Does this strain contain plasmids relevant to the patent process? If so, what physical containment level is required (National Institutes of Health Guidelines involving Recombinant DNA Molecules (i.e., P1, P2, P3 and P4 facility)?

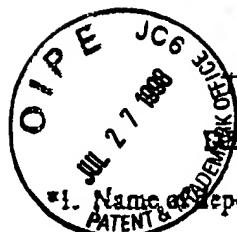
11. Isolated from?

\*The answers to these questions are recommended but not required.

FOR ATCC USE ONLY	
ATCC DESIGNATION _____	
DATE CULTURE RECEIVED _____	
DATE VIABILITY TEST COMPLETED _____	

FEE: 10 years license \$600 + 10 year certification \$150 + Viability testing \$100 (+ \$150 deposited upon arrival) + Expedite ATCC number \$15 + Return sample for approval if not examined (cost of frozen dried) \$10 + Proprietary (name) of cell/tissue/culture \$100  
 STORAGE: Cultures are stored for 10 years from date of deposit and for five years after the last request for a sample, as required under the rules of patent offices in most countries.

Form BP11 (Page 1 of 2)



FEB-02-00 18:11 FROM:

ID:

PAGE 6/6

12. In addition to those strains available under the Budapest Treaty and the European Patent Convention, do you wish the strain made available to:

a. Anyone who requests a culture (no restrictions on distribution from date of deposit or conversion to Budapest)  No

b. Requests to satisfy Patent Offices in countries not party to the Budapest Treaty? Please state which countries:  No other countries

After a U.S. Patent issues, the ATCC makes the culture available to anyone who requests it.

13. Do you wish the ATCC to inform you of all requests for this strain (Fee: \$330 for 30 years)? (This is allowed under the Treaty, but if you waive the right, the fee is reduced)  No

14. Would you like to be notified via fax or telephone of the ATCC number assigned to your strain (Fee: \$80.)?  Yes  
Fax No. (405) 271-4110 Telephone No. (405) 271-7385

Attention (name of individual) Dr. Eugen Koren

15. Deposit and viability certificates should be directed to:

Dr. Eugen Koren

Oklahoma Medical Research Foundation

825 NE 13th Street, Oklahoma City, OK 73104

16. Payment by check, or credit card (MasterCard or VISA), must accompany the deposit unless prior arrangements for billing have been made and approved. If arrangements have been made to bill you for services an invoice should be sent to (include P.O. #):

Credit Card # (Indicate MasterCard or VISA)

Expiration Date

Type or print the name shown on credit card

Signature

17. Name and address of attorney (to whom information will be made available if you complete):

18. Deposited on behalf of (must be completed): Dr. Eugen Koren, Oklahoma Medical Research Foundation

19. Additional comments:

I understand and agree that the deposit may not be withdrawn by me for the period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit), and that if a strain should die or be destroyed during the life of the patent, or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the case of viruses, cell cultures, plasmids and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

4/6/94

Eugen Koren

Date

Typed Name

*Eugen Koren*  
Signature

Address:

Oklahoma Medical Research Foundation

825 NE 13th Street, Oklahoma City, OK 73104

THIS FORM MUST BE COMPLETED IN ENGLISH

ADDRESS SHIPMENTS AND FORM TO THE ATTENTION OF:

Mr. Bobbie A. Brandon  
American Type Culture Collection  
12301 Parklawn Drive  
Rockville, Maryland 20852 USA

## COMBINED DECLARATION FOR PCT INTERNATIONAL APPLICATION(S)

## APPLICATION AND POWER OF ATTORNEY

ATTORNEY'S DOCKET NUMBER

OMRF143 CIP

*JOE*  
JUL 27 1995  
U.S. PATENT & TRADEMARK OFFICE  
As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought in the invention entitled:

Antibodies to Lipoproteins and Apolipoproteins and Methods of Use Thereof

the specification of which (check only one item below):

- is attached hereto.  
 was filed as United States application

Serial No. \_\_\_\_\_

on \_\_\_\_\_

and was amended

on \_\_\_\_\_ (if applicable).

- was filed as PCT international application

Number PCT/US95/08331

on 30 June 1995

and was amended under PCT Article 19

on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

## PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
PCT	PCT/US95/08331	30 June 1995	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

## Combined Declaration For Patent Application and Power of Attorney (Continuation)

(Includes Reference to PCT International Application)

ATTORNEY'S DOCKET NUMBER  
OMRF143 CIP

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

## PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
08/268,809	30 June 1994		X	

## PCT APPLICATIONS DESIGNATING THE U.S.

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)		

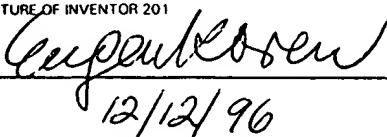
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Patrea L. Pabst - Reg. No. 31,284  
Madeline I. Johnston - Reg. No. 36,174

Send Correspondence to: Patrea L. Pabst, Esq. Arnall Golden & Gregory LLP 2800 One Atlantic Center 1201 W. Peachtree Street Atlanta, Georgia 30309-3450			Direct Telephone Calls to: (name and telephone number)  Patrea L. Pabst (404) 873-8794
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201	FULL NAME OF INVENTOR	FAMILY NAME Koren	FIRST GIVEN NAME Eugen	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY San Francisco	STATE OR FOREIGN COUNTRY California	COUNTRY OF CITIZENSHIP United States
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 600 Chestnut St., #203	CITY San Francisco	STATE & ZIP CODE/COUNTRY California 94133
202	FULL NAME OF INVENTOR	FAMILY NAME Koscec	FIRST GIVEN NAME Mirna	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY Oklahoma City	STATE OR FOREIGN COUNTRY Oklahoma	COUNTRY OF CITIZENSHIP Croatia
	POST OFFICE ADDRESS	POST OFFICE ADDRESS Apt. D 12418 Trail Oak Drive	CITY Oklahoma City	STATE & ZIP CODE/COUNTRY Oklahoma 73120
203	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201 	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE 12/12/96	DATE	DATE

**Mixed Declaration For Patent Application and Power of Attorney (Continued)**  
 Includes Reference to PCT International Applications

ATTORNEY'S DOCKET NUMBER  
 OMRF143 CIP

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:**

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
08/268,809	30 June 1994	X		

**PCT APPLICATIONS DESIGNATING THE U.S.**

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Patrea L. Pabst - Reg. No. 31,284  
 Madeline I. Johnston - Reg. No. 36,174

Id Correspondence to: Patrea L. Pabst, Esq. Arnall Golden & Gregory LLP 2800 One Atlantic Center 1201 W. Peachtree Street Atlanta, Georgia 30309-3450			Direct Telephone Calls to: (name and telephone number)  Patrea L. Pabst (404) 873-8794
FULL NAME OF INVENTOR	FAMILY NAME Koren	FIRST GIVEN NAME Eugen	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY San Francisco	STATE OR FOREIGN COUNTRY California	COUNTRY OF CITIZENSHIP United States
POST OFFICE ADDRESS	POST OFFICE ADDRESS 600 Chestnut St., #203	CITY San Francisco	STATE & ZIP CODE/COUNTRY California 94133
FULL NAME OF INVENTOR	FAMILY NAME Koscec	FIRST GIVEN NAME Mirna	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY Oklahoma City	STATE OR FOREIGN COUNTRY Oklahoma	COUNTRY OF CITIZENSHIP Croatia
POST OFFICE ADDRESS	POST OFFICE ADDRESS Apt. D 12418 Trail Oak Drive	CITY Oklahoma City	STATE & ZIP CODE/COUNTRY Oklahoma 73120
FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

ATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202 <i>Mirna Koscec</i>	SIGNATURE OF INVENTOR 203
	DATE 12 - 09 - 1996	DATE